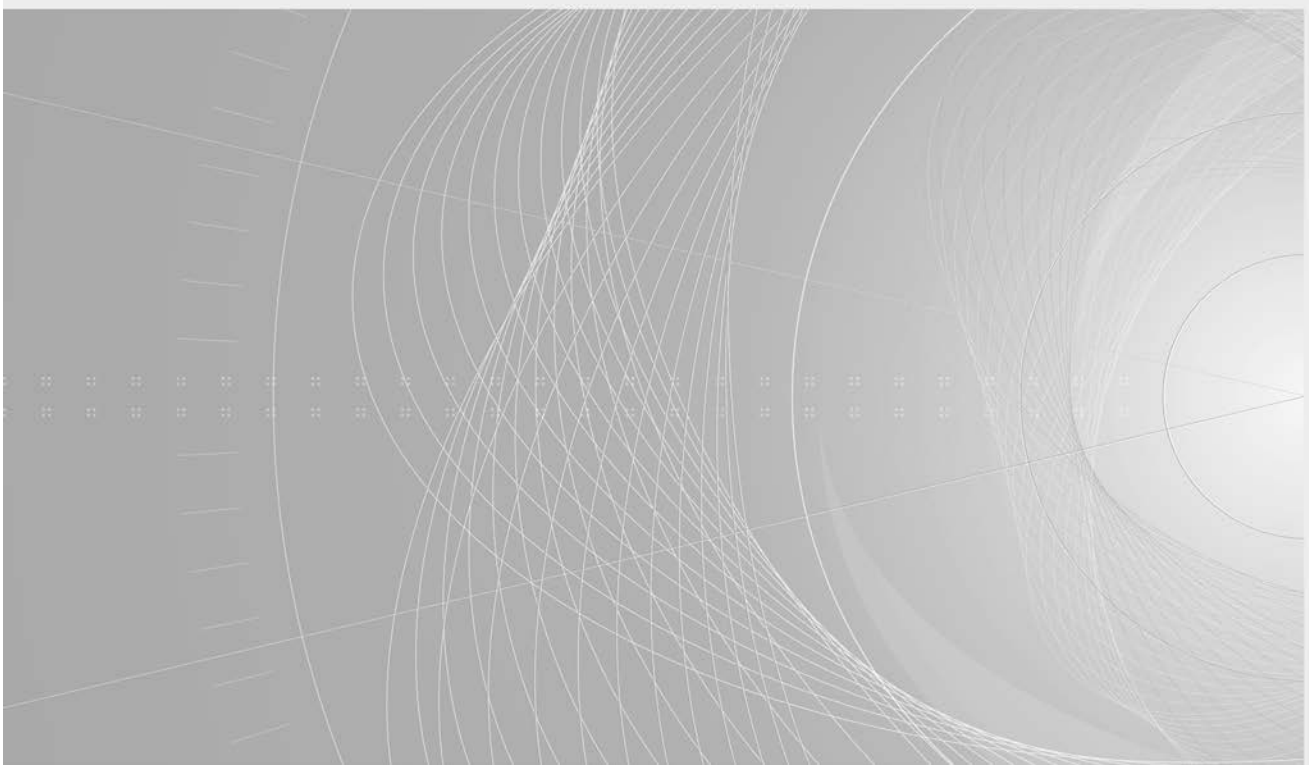




IECEE GUIDANCE DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Guidance for IECEE Factory Inspectors to fill the Factory Surveillance Report





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Foreword

Scope

To be determined

Document Owner

CFS

History of changes

Revision Date	Brief summary of changes
2018-06-27	The document number OD-G-4001 has been changed to GD-4001 as per OD-2059, Edition 1.2
2018-01-29	Changes have been made to the title of the OD as well as the Factory Surveillance Report Section in the Foreword, clauses 1.6 and 9, as well as NCS section.

Effective date	Next maintenance due date
2018-06-05	2021-06-05

The aim of this Guidance Document is to provide guidance for IECEE Factory Inspectors (in the following referenced as “Inspectors”) undertaking Factory Surveillance Services and completing form OD-4001 Factory Surveillance Report.

This part gives instruction to Inspectors. It gives detailed information on what the Inspector is looking for and how he makes the assessment. The aim is to ensure that, irrespective of which Surveillance Body conducts the Surveillance, the same criteria are used to assess whether the Manufacturer's premises meet the Minimum Requirements of the IECEE CB-FSS.

Pre- or Post-certification initial assessment of the production

Completion of the report serves as a verification that the quality system and the testing procedures as applied by the Manufacturer will ensure the compliance with the requirements of the IECEE CB-FSS.

The visit has to be pre-announced to ensure that the contact person, knowledgeable of the quality system is available.

The Manufacturer shall be made aware that at the time of the visit all relevant documentation and test equipment shall be available and ready for inspection.

Factory Surveillance

Completion of the report serves as a periodic verification that the quality system and test procedures are still maintained and are in compliance with the current requirements of the IECEE CB-FSS.

Additional information

Due to confidentiality reasons, it might be necessary to issue two or more reports if the same factory is used for more than one customer, product, brand name and / or certificate holder.

Due to application of basic and additional requirements the time frame for FSS will be more than 4h as today for Factory Inspections.

Factory Surveillance Report

Note: The Inspectors are requested to write the report in a legible manner.

Surveillance carried out by

- CB-FSB: enter name of your Surveillance organization (CB-FSB – CB Scheme Factory Surveillance Body).
- Reference number: enter your reference number. The reference number has to be indicated at each single page.

Note

- a) Please tick as appropriate.
- b) Explain clearly, and in each case, why you consider a question as not applicable.
- c) Unless self-evident all “yes” and ‘no’ answers require explanation on the “**Inspector’s Evaluation Informative page**” or in the provided field of the report.

Records

The records need to be carefully reviewed.

The minimum period for record retention shall not be less than the period between two Surveillance Activities. The Manufacturer shall state the retention time.

1 General Information

1.1 This is the place the Inspector visits. Enter the actual name and manufacturing address. Give just enough information to identify the Manufacturer.

1.2 Enter name and function of the manufacturer’s representative; also when the manufacturer’s representative was not present during the Surveillance. The manufacturer’s representative is considered as the person who shall be contacted first when entering the factory and to whom correspondence on items related to IECEE-CB-FSS (Factory Surveillance Service) is to be send.

1.3 Enter name and function of the main people involved in the Surveillance

1.4 Tick box to indicate type of Surveillance(s).

The Surveillance can cover more additional and special requirements which may be based on legal requirements, scheme requirements, technical requirements or NCB requirements (if applicable). These requirements are compiled in annexes to the report which are provided by the NCBs who want to participate in this service. For all requested special requirements the appropriate annex is selected, used, filled in and attached to the report. All used attachments are reported in clause 17.3 of this report.

1.5 Products covered by this surveillance

Enter the category, the product, the PID-Number and its version/issuing date. Multiple products can be entered into the table.

1.6 Enter name of Inspector and date of the Surveillance.

Remember to always complete the report even if there is no production of certified products. All details about the testing, test equipment and calibration are equally important even if other products are in production.

2 Verification of purchased components and materials which have a safety implication on the certified product (Incoming Inspection)

2.1 The Inspector has to look for procedures used by the Manufacturer to ensure compliance of materials, components and sub-assemblies. The personnel shall have clear instructions on what and how to perform checks. If applicable there shall be instructions as to which Certification Marks may have to appear on the components/products.

2.2 Self-explanatory

2.3 Self-explanatory

2.4 If a documented procedure exists please give reference.

If no documented procedure exists the procedure in place shall be observed and described as found.

The inspector's description of the procedure should cover at least the following items:

- What action is taken by the Manufacturer, if the product fails a required test?
- Is the non-conforming product clearly identified and/or segregated?
- What are the instructions as to the disposition of non-conforming products?
- Does the system ensure that corrected items are again subjected to appropriate tests/Surveillances?
- Are non-conforming products recorded?

2.5 Regarding this question the Inspector has to evaluate the procedure and to verify whether the procedure is sufficient.

The Inspector has to confirm that the applied procedure is satisfactory and will continue to be so. If the procedure applied is not satisfactory, please report details.

2.6 Self-explanatory

2.7 Self-explanatory

3 Production Control, Inspection and Routine Tests

3.1 Look for instructions and check if they are understood and followed by all personnel involved.

3.2 Is there sufficient information available to ensure that parts having an impact on the safety of the finished products are properly manufactured/ assembled (mounted) and tested.

3.3 There shall be evidence demonstrating that the production/assembly process is controlled in such a way that the finished products are identical to the certified version.

3.4 Make sure that no product can pass the 100 % Routine Test without being tested.

3.5 Self explanatory

3.6 Enter on the Test Data Sheet the routine tests witnessed (indicate W). For tests not witnessed, the production line test records shall be reviewed and data entered in the table (indicate R). Use the free space to describe other tests applied. If more than one product category or insulation class is inspected use individual test data sheet for each product category and/or insulation class. For tests not witnessed, the function of the test equipment is still to be verified (indicate in 4.1).

Example of how to complete the table on Test Data Sheet (if applicable)

Annex 1 - Test Data sheet – Routine Tests

<input type="checkbox"/> No production	
<input checked="" type="checkbox"/> Production seen	Certification mark (if any): IMQ, VDE
Product Category (e.g. HOUS): HOUS	Kind of product (e.g. vacuum cleaner): Microwave oven
Type number: M36	Electrical Insulation Class: I
Rated voltage: 230 V	

TESTS		% check	Test value applied	Time	Factory limits applied:	Failure indicated by	Remarks	W
								R
a	Earth continuity	100 %	12 V d.c. 10 A	2 s	0,2 Ohm Ohm (max.)	Instrument Lamp	Including resistance of the supply cord & plug	W
b	Insulation resistance	100 %	500 V d.c.	4 s	2 MOhm (min.)	Instrument		W
c	Leakage current	5 %	230 V a.c.		5 mA (max.)	Instrument		R
Dielectric strength	Basic insulation	100 %	1000 V a.c.	2 s	30 mA (max.)	Instrument, Lamp Buzzer	Manual reset needed	W
	Supplementary insulation	n/a	V	s	mA (max.)			
	Reinforced insulation	n/a	V	s	mA (max.)			
e	Load deviation	100 %	230 V a.c.	5 s	+ 5 – 10%	Instrument	(e) cold	R
f	Functional test	100 %	230 V a.c.			no function	(f) yes	W
	Microwave leakage	100 %	230 V a.c.		50 W/m ²			W

e Indicate method used (hot/cold, at mains voltage, low voltage resistance check, etc.).

f Are all controls and components checked during the test ?

W Test witnessed by the inspector, R = according to records

3.7 Check if there are differences in requirements between organization and if they are complied with (if applicable, eventually transferred into an annex of the report for national or other differences)

3.8 If a documented procedure exists please give reference.

If no documented procedure exists the procedure in place shall be observed and described as found.

The inspector's description of the procedure should cover at least the following items:

- What action is taken by the Manufacturer, if the product fails a required test?
- Is the non-conforming product clearly identified and/or segregated?
- What are the instructions as to the disposition of non-conforming products?
- Does the system ensure that corrected items are again subjected to appropriate tests/inspections?
- Are non-conforming products recorded?

Regarding this question the Inspector has to evaluate the procedure and to verify whether the procedure is sufficient.

The Inspector has to confirm that the applied procedure is satisfactory and will continue to be so. If the procedure applied is not satisfactory, please report details.

3.9 The Manufacturer shall provide visual identification of any non-conforming product. If special segregation areas are used, make sure they are clearly marked as such.

3.10 In case of failures detected, verify that the Manufacturer has a procedure which ensures that corrected items are again subjected to appropriate tests/inspections.

3.11 Record shall be legible and identifiable to the products and should specify tests conducted.

3.12 Self explanatory

4 Functional Check on Test and Measuring Equipment used for Safety Tests (Dummy Test)

4.1 Verify that the procedure how to perform the functional test is available and understood by the operator(s). If no written instruction is available, describe on Inspector's Evaluation informative page how instructions are given and how understanding is verified.

4.2 Inspector shall check that the test equipment is functioning as planned even if certified products are not presently produced.

4.3 The Inspector shall verify that the Manufacturer has a system that ensures that no products are shipped to a client before the correct functioning of the test equipment has been checked.

As a minimum daily checks are recommended at the end of the daily production, for lot production taking less than a day a check before and after the lot has been produced is recommended.

4.4 Ensure that all wiring is included in the test.

4.5 The simulated failure (Dummy, if used) shall represent the tripping limits used by the manufacturer during testing of the certified product. Directly short cut of the test pins is not acceptable.

4.6 Operators shall be instructed on what action to take if a test proves to be unsatisfactory. The Inspector shall check that the operator clearly understands these instructions.

4.7 The inspector shall verify that the manufacturer will identify all products checked since the previous dummy test and will test these products again before shipment to the client.

4.8 Check that corrective action is recorded and include information of re-tested products.

4.9 Record shall include equipment identity no.

4.10 Self explanatory

5 Products seen in Production during visit

If there is production, record the kind of product(s), type(s) and applicable Certification Marks(s) on the Inspector's Evaluation informative page. If Certification Marks are not applied but nevertheless referenced in sales information, installation instructions, manuals, etc. please state accordingly.

If there is no production of certified products, indicate if similar products were manufactured and whether or not similar testing is applied.

For each kind of product per product category / electrical insulation class that can be produced by the manufacturer a separate Test Data Sheet is to be completed.

6 Calibration of Safety Test and Measuring Equipment

6.1 The Inspector shall check that the Manufacturer maintains an effective calibration/verification program.

The calibration/verification of the safety test and measuring equipment should preferably be performed at least once a year depending on usage and the results of previous calibration/verification. Less frequent calibration/verification need to be explained by the Manufacturer to be appropriate e.g. by reasons of previous calibration/verification results (no trend shift) or other engineering considerations. Inspector needs to evaluate if this is reasonable.

6.2 This paragraph is covering the calibration of the reference equipment that is used for the verification of the test and measuring equipment, as far as this reference equipment is available with the manufacturer. (Information of the calibration/verification of the test and measuring equipment on the production line is to be given in paragraph 6.1).

6.3 Self-explanatory.

6.4 All calibration/verification undertaken shall be traceable to national/international standards of measurement.

Records shall clearly identify the equipment and shall include as a minimum:

- date of calibration/verification
- test results (it is desirable that actual values be recorded – acceptance criteria shall be defined.)
- next date of calibration/verification
- action taken, if found to be out of calibration/verification

Note: some NCB's require that records are signed

6.5 Self-explanatory

6.6 Self-explanatory

7 Handling and Storage

7.1 It is to be verified that the handling and storage of components and materials to be used for production will ensure that no damage/reduction of properties will occur. Attention is to be paid to e.g. identification, environmental conditions, Electrostatic Discharge (ESD); First In First Out (FIFO) principle.

7.2 The handling and storage of finished products shall ensure that these products will remain electrical and mechanical safe and will continue to comply with the applicable certification standard(s).

8 (Reserved for future use)

9 Verification of Construction Identity against PID (Product Identification Document)

The PID has been originated during the type approval test and shows all descriptive technical details about the produced certified product, see OD-2020-F6.

9.1 The inspector shall verify that the PIDs (see cl. 1.5) are available.

9.2 The inspector shall verify that the product in production is the same as described in the PID. As part of this verification the inspector has to confirm that the materials and components used in the product are the same as listed in the PID. In case that other materials and components are found in the product, the inspector shall list all materials and components not listed in the PID on a separate Inspector's Evaluation Informative page.

If the inspector identifies components that are not suitable he shall list those on a Non Conformity Sheet.

9.3 The inspector shall verify that the product in production is assembled and finished as shown in the PID. This includes labels and warnings. He has to confirm that no constructional changes or design changes have been made. In case that any modifications are found in the product the inspector shall list all modifications to the PID on a separate Inspector's Evaluation Informative page.

If the inspector identifies modifications that are not acceptable, he shall list those on a Non Conformity Sheet.

10 Follow up on corrective actions from previous surveillances

The Inspector shall verify that the corrective actions from previous surveillance have been completed and implemented.

If the corrections were not implemented a new NCR shall be issued.

The Inspector shall be convinced that any corrective action(s) taken by the Manufacturer are acceptable.

11 Quality Management System

Please mention the name of the organization which assessed or certified the Manufacturer. State type and issued date of the certification.

Note: Combined Surveillances/ audits can be organized if the Quality System of the Manufacturer is audited by the same organization as the Body carrying out the subjected factory Surveillance.

12 (Reserved for future use)

13 (Reserved for future use)

14 Customer complaints

14.1 Self-explanatory

14.2 Check if the management reviews customer complaints. N/A means that no complaints were received.

14.3 The records need to be carefully reviewed. N/A means that no complaints were received.

14.4 Self-explanatory N/A means that no complaints were received.

14.5 Self-explanatory N/A means that no complaints were received.

14.6 Self-explanatory N/A means that no complaints were received.

15 Control of product changes

Note: N/A can be used only for Pre-certification surveillance visits.

15.1 Self explanatory

15.2 Evidence that the reference is controlled by the certificate holder shall be by signature or other methods that link the reference to the certificate holder.

15.3 The Inspector has to verify that the applied procedure is satisfactory and will continue so.

15.4 Self explanatory

15.5 Note the statement of the Manufacturer.

If the Manufacturer made constructional changes to the product without a written authorization from the Certificate Holder, specify the changes made on the Non Conformity Sheet'.

16 (Reserved for future use)

17 Inspector's Evaluation

17.1 All unsatisfactory findings shall be recorded. The Manufacturer may propose suggestions as to how he intends to correct the non-compliances identified. Please note also such commitments. Where appropriate, the Certificate Holder shall also confirm the proposed corrective actions he intends to take to the NCB with special requirements being checked during the Surveillance – if applicable.

Report the findings requiring corrective actions on the page entitled 'Non Conformity Sheet'

Report general matters such as change of address, name change, etc. on the page entitled 'Inspectors evaluation – Informative'

Note: Use separate Inspector's Evaluation Pages for different NCB's or certificate holder if necessary, e.g. for reasons of confidentiality.

17.2 Inspector's Recommendations:

Ticking of any box is based entirely on the Inspector's judgment.

Any resulting consequences shall be notified by the NCB with special requirements being checked during the Surveillance to the Certificate Holder/ Manufacturer and the Surveillance Body in writing.

If a limited number of major unsatisfactory findings, where safety not directly affected, is reported and where in the Inspector's judgment an early routine Surveillance is not necessary, then the Inspector may cross out 'early routine Surveillance recommended'. Within the 'Non Conformity Sheet' a time frame for 4 weeks is appropriate for proposed corrective actions.

If "safety directly affected" the inspector has to inform his responsible CB-FSB immediately to allow appropriate actions.

17.3 Tick box if attachments are added.

State the number of the attachment pages. If an attachment is not used the number of pages shall show 0 (zero).

General remarks:

The Manufacturer shall be made aware of the contents of the report.

The Inspector is required to give a copy to the Manufacturer's contact person who shall sign for the receipt.

Any matter which may be of an informative character may be recorded on the Inspector's Evaluation Informative page.

This may include:

- technical matter discussed during the visit
- matters to be checked in greater details during the next Surveillance visit
- how and where the Certification Mark is applied
- Manufacturers' working hours, holidays or closing days

Non-Conformity Sheet (NCS)

The NCS shall be used for documentation of Non-Conformities (NCs) found during the surveillance visit. More information can be provided on the attachments as part of the NCS form.

The following hints shall be considered.

- 1) For each kind of non-conformity create a separate NCS
- 2) Group non-conformities of the same kind on one NCS together
- 3) Describe the findings sufficiently to facilitate traceability
- 4) Give reference to the clause of the surveillance report concerned
- 5) Ask the manufacturer to take sufficient efforts on the root cause analysis to find out the real rational for the NC. Explain that only the deep root cause analysis can avoid similar NCs in the future.
- 6) Ask the manufacturer to provide a traceable CA fitting to the issues identified in the root cause analysis.

The sequence of tasks for the surveillance inspector is the following:

- 1) Do the FSS and fill in the OD 4001 including NCS as many as needed.
- 2) Do the follow-up of the NCS by evaluating the root cause analysis and the CAs provided by the manufacturer within the time frame allowed.
- 3) Acceptance shall be documented on the NCS.
- 4) Evaluate the evidence showing the implementation of CA provided by the manufacturer.
- 5) Confirm on the NCR the efficient implementation of the CA.
- 6) Keep and control the time schedule for solving NCs and implementation of CAs.

On request of the manufacturer it is possible to issue a new FSR with the updated and solved NCs and a new final evaluation according to clause 17.2.

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